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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,767

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Rajinder Singh

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05/14/2008

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EXAMINER

CHU, YONG LIANG

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

05/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,767	Applicant(s) SINGH ET AL.	
	Examiner YONG CHU	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25, 28-34 and 38-46 is/are pending in the application.
- 4a) Of the above claim(s) 30-34 and 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 28-29, and 42-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 25, 28-34, and 38-46 are pending, and claims 30-34 and 38-41 are nonelected subject matter, and was withdrawn from further in the previous Office action dated on 10/25/2007.

Priority

This application is a 371 of PCT/US03/32947 filed on 10/15/2003, which claims the benefit of U.S. Provisional Patent Application No. 60/419,012, filed on 10/15/2002.

Response to Argument

Rejection of claims under 35 U.S.C. §102(b)

Applicant's arguments over rejection of claims 25, 42, and 43 under 35 U.S.C. §102(b) over the Sainsbury's teaching have been considered, and are found persuasive. Since the prior art teaches only the compound, but not a composition comprising the compound thereof. The rejection has been withdrawn.

Applicant's arguments over rejection of claims 25, 28-29, and 42-46 under 35 U.S.C. §102(b) over the teachings of the elected species of a composition comprising the Compound 281 (Peakadale Catalog # PFC-1019) have been considered, but are found not persuasive. According to the statement from Peakadale Inc, the company started sent advertisement flier of the Compound 281 to their potential customer on 1990s for drug screening purpose in drug discovery research. According to their record, the first sale of the compound was on 1999. Since the claimed compound was taught

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for drug screening purpose, it is common knowledge to one skilled in the art that an appropriate dilutes or carrier is necessarily needed for a drug candidate compound to be screened for drug discovery purpose, see the drug screening protocol for drug discovery by Wabnitz et al., *Rapid Communications in Mass Spectrometry*, 2002, Vol. 16, p.85-91. To screen a compound for drug discovery, it has to be in an appropriate formulation in order to expose the compound to either an enzyme or cells or animal *in vitro* or *in vivo*. Therefore, the instantly claimed composition is an inherent property of the teaching by Peakdale Catalog. In order to rebut the rejection, Applicants need to provide the Office the original a copy of the entire Peakdale catalog that Applicants used when they ordered the product, and any information they know for using the compounds for drug screening purpose.

Alternatively, claims 25, 28-29, and 42-46 are subject to the following further rejections:

Claim Rejections - 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

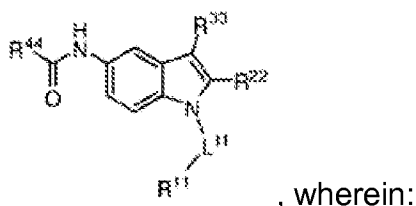
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25, 28-29, and 42-46 are rejected under 35 U.S.C. 103 (a) as unpatentable over the Peakadale's teachings in view of Wabnitz's teaching on drug candidate screening and discovery, *Rapid Communications Mass Spectrum*, 2002, Vol. 16, p.85-91.

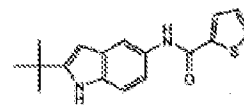
Applicants' claims relate to a composition comprising a compound of Formula (I)



L¹¹ is a bond; **R¹¹** is H; **R²²** is C₁₋₆ alkyl; and **R³³** H or C₁₋₃ alkyl; and **R⁴⁴** is an optionally substituted C₃₋₆ monocyclic heteroaryl, and the remaining substituents are as defined in claim 25.

Determination of the scope and content of the prior art (MPEP §2141.01)

Peakadale catalog discloses a specific compound PFC-1019



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disclosed in IDS. Peakadale Inc. made and sold this compound for drug screening candidate in the research on new drug discovery before 2000.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the Peakadale's teaching and the instant application is the prior art teaches a compound, and the use for drug screen in drug discover research, but does not teach a composition comprising the compound.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

However, such difference would have been obvious to one ordinary skilled in the art in view of the common knowledge of drug screening as illustrated by the Wabnitz's teaching on drug candidate screening and discovery. To screen a compound for drug discovery, it has to be in an appropriate formulation in order to expose the compound to either an enzyme or cells or animal *in vitro* or *in vivo*. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

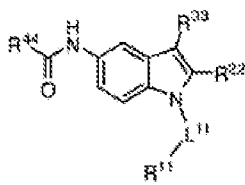
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 28-29, and 42-46 are rejected under 35 U.S.C. 102 (b) as being anticipated by Fritz et al., *U.S. Patent No. 5,998,630* ("the '630 patent").

Applicants' claims relate to a composition comprising a compound of Formula (I)

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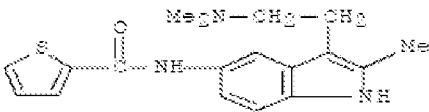


, wherein:

L^{11} is a bond; R^{11} is H; R^{22} is C_{1-6} alkyl; and R^{33} H or C_{1-3} alkyl; and

R^{44} is an optionally substituted C_{3-6} monocyclic heteroaryl, and the remaining substituents are as defined in claim 25. There is no definition of “ C_{1-3} alkyl” in the specification, and this term is given the broadest interpretation in light of the specification according to paragraph [0077], which defines alkyl group as optionally substituted or unsubstituted under “heteroarylalkyl”.

The '630 patent discloses a pharmaceutical formulation which comprises a

specific compound  (CAS CN 189806-65-3) as Example

74, in association with a pharmaceutically acceptable carrier, diluents or excipients.

This prior art composition anticipates the instantly claimed genus, wherein:

L^{11} is a bond; R^{11} is H; R^{22} is C_{1-6} alkyl; and R^{33} is an amino-substituted H or C_{1-3} alkyl; and R^{44} is an optionally substituted C_{3-6} monocyclic heteroaryl.

Claim Rejections - 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

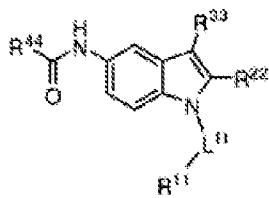
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25, 28-29, and 42-46 are rejected under 35 U.S.C. 103 (a) as unpatentable over `630 patent.

Applicants' claims relate to a composition comprising a compound of Formula (I)



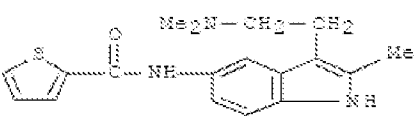
, wherein:

L¹¹ is a bond; R¹¹ is H; R²² is C₁₋₆ alkyl; and R³³ H or C₁₋₃ alkyl; and

R⁴⁴ is an optionally substituted C₃₋₆ monocyclic heteroaryl, and the remaining substituents are as defined in claim 25.

Determination of the scope and content of the prior art (MPEP §2141.01)

The `630 patent discloses a pharmaceutical formulation which comprises a

specific compound  (CAS CN 189806-65-3) as Example 74, in association with a pharmaceutically acceptable carrier, diluents or excipients.

This prior art composition anticipates the instantly claimed genus, wherein:

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L¹¹ is a bond; **R¹¹** is H; **R²²** is C₁₋₆ alkyl; and **R³³** is an amino-substituted H or C₁₋₃ alkyl; and **R⁴⁴** is an optionally substituted C₃₋₆ monocyclic heteroaryl.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the '630 patent and the instant application is the prior art teaches a composition comprising the specific compound (Example 74) wherein **R²²** is a methyl group, for inhibiting HCV infection, but does not teach a composition comprising a specific compound, wherein **R²²** is other C₁₋₆ alkyl group, such as t-butyl or neo-pentyl. However, the '630 patent also teaches a compounds with **R²²** as C₁₋₄ alkyl.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The instantly claimed invention would have been obvious over the '630 patent teachings, because one skilled in the art would have been motivated to prepare homolog of the compounds with **R²²** as the other C₁₋₆ alkyl group with the expectation of obtaining compounds which could be used in the related composition for pharmaceutical utility. To those skilled in the chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members, In re Wilder, 563 F.2d 457, 195USPQ 426 (CCPA 1977), and MPEP§2144.09. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds or composition would possess similar activity (i.e. pharmacological use). Therefore, the instantly claimed composition would have been suggested to one skilled in the art.

Conclusions

No claim is allowed.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu, Ph.D./
Patent Examiner
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